

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

PB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

08/913,139 02/09/98 ZENTGRAF H 0484-029-999

HM22/0508

PENNIE & EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

EXAMINER

NDIANA P

ART UNIT

PAPER NUMBER

1644

14

DATE MAILED:

05/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/913,139

Applicant(s)

Examiner

Nolan

Zentral et al.

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

Responsive to communication(s) filed on 2/11/00 and 4/20/00.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

Claim(s) 1-10 is/are pending in the application.

Of the above claim(s) 5-10 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-3 is/are rejected.

Claim(s) 4 is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892 Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948 Other _____

Office Action Summary

Part III DETAILED ACTION

1. This application is a 371 of PCT/DE96/00369.
2. Claims 5-10 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1-2 are rejected under 35 U.S.C. 102(a) based upon a public use or sale of the invention.

Janssen et al., (J. Biol. Chem., Vol 270, No. 19, pages 11222-11229, U) teaches anti-histidine antibodies which bind a histidine portion in a fusion protein, wherein said histidine region is 6 residues long (see page 11223, in particular).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and

invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3 are rejected under 35 U.S.C. § 103 as being unpatentable over Janssen et al., (U), in view of Sevier (W).

Janssen et al., has been discussed supra.

The claimed invention in claim 3 differs from the prior art teachings only by the recitation of a monoclonal antibody which binds the histidine tagged fusion protein. However, Sevier et al. (Clin Chem. 27: 1797-1806, 1981), teach the making of monoclonal antibodies from known antigens (pg 1797, column 2, in particular) and that monoclonal antibodies are more homogenous, specific and more easily available than polyclonal antibodies (abstract, in particular).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the six histidine residue tag taught by Janssen et al., in the method taught by Sevier et al., to produce monoclonal antibodies that bind six histidine residue tagged fusion proteins with the expectation that monoclonal antibodies as taught by Sevier et al., are more specific, homogenous and more easily available than polyclonal antibodies and are therefore more useful in diagnostic assays than polyclonal antibodies.

5. Applicant is notified claim 4 is objected to because it depends upon a rejected claim.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

7. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.



Patrick J. Nolan, Ph.D.
Patent Examiner, Group 1640
May 8, 2000